Substance of Interview Held on March 7, 2006:

On March 7, 2006, Debi Whitson and Matt Harlow (Reg. No. 52,994) participated in an interview with Examiner Porter. In the interview, Applicant explained that HL7 laboratory records have been used exclusively for traditional laboratory tests, such as blood tests, and that including such information as medical history, environment, and symptoms in an HL7 laboratory record is novel. Applicant discussed evidence of this in the form of various articles explaining medical industry standards that only recognize traditional laboratory tests in HL7 laboratory records.

Applicant also explained that electronic medical records are a specific type of record that includes patient-specific, confidential information submitted by a physician, and that the prior art references cited in the previous Office Action did not relate to electronic medical records. The Examiner recommended amending the claims to include these aspects of an electronic medical record.

Remarks:

Claims 1–7, 9–11, 13, 14, and 17–21 were previously pending with claims 1, 18, and 20 being independent. Claims 1, 4, 5, 14, 17, 18, and 20 are presently amended and claim 3 is cancelled. Therefore, claims 1, 2, 5–7, 9–11, 13, 14, and 17–21 are currently pending with claims 1, 18, and 20 being independent.

In the Office Action dated January 6, 2006 ("OA"), claims 4, 5–6, 11, 14, and 17 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 3–5, 9, 11, 18–19, and 21 were rejected under 35 U.S.C. § 102(e) as being anticipated by Kraftson, U.S. Patent No. 6,151,581. Claims 2, 10, and 17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kraftson in view of Oyama, U.S. Patent No. 5,496,175. Claims 6–7 and 13–14 were rejected under 35 U.S.C. § 103(a)

as being unpatentable over Kraftson in view of Official Notice. Finally, claim 20 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Kraftson in view of Johnson, U.S. Patent No. 5,664,109, and Evans, U.S. Patent No. 5,924,074.

Applicant's Response to Official Notice

In the Office Action dated July 5, 2005, the Examiner took Official Notice regarding use of HL7, ANSI, and ASTM. (Page 11). Applicant agrees only with the assertion that "HL7, ANSI, and ASTM are well known in the art for establishing transmitting and formatting standards for data."

The Application Invention

The application invention involves a novel method of enabling a patient to submit medical information directly to the patient's electronic medical record (EMR), wherein the EMR contains patient-specific, clinical information regarding the patient's health. The dictionary defines "clinical" as follows:

> of, relating to, or conducted in or as if in a clinic (as a medical clinic): as a: involving or depending on direct observation of the living patient <~diagnosis> <~examination> b: observable by clinical inspection <~tuberculosis> c: based on clinical observation <~picture> <~treatment>

WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 423 (2002).

Therefore, the electronic medical records that are acted upon by the claimed invention include information that is specific to a patient and that is obtained from direct observation within a medical clinic. Thus, these electronic medical records are not just any records containing medical information, but are a particular class of medical records maintained by healthcare providers, such as doctors, and that include diagnoses and other notes and comments pertaining to a particular patient recorded by the doctor upon observation of the patient. In other words, the EMR is an electronic version of the patient's medical "file" that

contains information personal to the patient and that is used by medical professionals to treat the patient.

As explained in the application, the submission of information to a patient's EMR is regulated by privacy laws such as HIPAA (which relates to the broad class of health information described as "individually identifiable health information" (http://www.hhs.gov/ocr/hipaa/)), which require healthcare providers to maintain the privacy of a patient's medical history and thus restrict access to the patient's medical records, including electronic medical records. Thus, healthcare providers are required to limit the manner in which a patient's personal information is added to an EMR database to ensure that only authorized personnel view the information stored in the database. For example, prior art methods of submitting a patient's medical information to an EMR involve a healthcare provider soliciting medical information from the patient and the provider manually recording the information into the EMR or recording the information on paper and giving the paper to a staff member who manually submits the patient's medical information to the EMR.

The application invention improves upon the prior art methods by enabling the patient to add personal medical information to his or her EMR with little or no assistance from a healthcare professional or staff member while preserving the privacy of the EMR database. Notably, the application invention accomplishes this without requiring a re-design of existing EMR database management software or software used by healthcare professionals to access patients' electronic medical records.

Particularly, the method of the application invention involves receiving a questionnaire from a patient, wherein the patient has filled out the questionnaire with the patient's pertinent medical information including medical history, environment, and symptoms. The questionnaire is then scanned to convert the information on the questionnaire to computer-processable data. The computer-processable data is structured according to a Health Level Seven (HL7) medical data communications protocol and communicated to an EMR interface engine for addition to the patient's personal EMR in

an EMR database. The HL7 protocol was developed to enable cross-platform communication of electronic medical record data between computer systems, such as a laboratory computer system and a physician's office computer system. According to the exemplary embodiment of the invention disclosed in the application, the data received from the patient is structured to simulate an HL7 laboratory record to render it compatible with an EMR interface engine. In other words, the interface engine treats the patient-submitted data as if it were received from a laboratory computer system. The application invention thus builds upon the HL7 protocol—which is already commonly used by physicians' computer systems—by enabling the computer systems to receive medical information directly from a patient and add the information to the patient's electronic medical record.

The patient submits the questionnaire prior to an appointment with the doctor, such as while the patient is in the waiting room on the day of the appointment. The information is scanned and added to the patient's personal EMR nearly instantaneously to enable the doctor to view the information as part of the patient's personal medical record at the appointment. Thus, the invention ultimately saves the doctor time by eliminating the need for the doctor to ask the patient questions about his or her health status, write the questions down, and ask a staff member to add the information to the patient's EMR.

Summary of U.S. Patent No. 6,151,581 to Kraftson

Kraftson discloses a system and method for the "acquisition, management and processing of patient clinical information and patient satisfaction information received from a group of physician practices to provide practice performance information." (Kraftson, col. 2, lines 52–56). Kraftson uses the information gathered from multiple practices to create statistical summaries of practice results, including effectiveness of treatment, patients' perception of the quality of the healthcare, and costs. (*Id.*, col. 5, lines 23–37, 52–62).

Kraftson discloses using machine-readable survey forms to collect

information from both doctors and patients, scanning the survey forms, converting the information on the forms to a pre-determined data format, and storing the data in a database for further processing. (*Id.*, col. 5, lines 1–13; col. 6, lines 1–8). The survey forms are completed by the patient and the physician "during a treatment session at [the] physician's practice" or after the treatment session. Importantly, the patient's portion of the survey relates exclusively to satisfaction with the physician's services. (*Id.*, col. 6, line 3; col. 11, lines 15–17; col. 12, lines 14–24; tables 1A, 1B; FIGs. 2A–2C). Furthermore, the patient's portion of the survey is completely anonymous, therefore information submitted by a patient cannot be associated with that patient. (*See id.*, FIGs. 2B, 2C (illustrating patient surveys that include the declaration "THIS SURVEY IS TOTALLY ANONYMOUS")). Thus, Kraftson expressly discloses that the information collected by a patient is not associated with a particular patient, and therefore cannot be added to a patient specific electronic medical record.

The information submitted by the patient and the doctor is converted to "data records having a predetermined format." (*Id.*, col. 7, lines 8–9). Note that the information is converted to "data records," *not* medical records. The data records created by the system disclosed in Kraftson are entirely different than medical records. For example, the data records are created according to a format that facilitates statistical analysis of the information, such as storing prescription information in a sub-database separately from other elements of the information. (*Id.*, col. 7, lines 45–53). The data records are not used by a physician during a treatment session, and are never added to a patient's electronic medical record.

Thus, there are several notable differences between the method disclosed in Kraftson and the method of the application invention. First, the method of the application invention adds the information collected by the patient into the patient's patient-specific electronic medical record for use during a doctor's visit, while the method of Kraftson stores the satisfaction information collected from the patient in anonymous data records for statistical analysis after the doctor's visit. Second, the method of the

application invention collects health status information from the patient while the method of Kraftson collects satisfaction information from the patient. Third, the method of the application invention receives information from the patient prior to a doctor's visit, while the method of Kraftson receives information from the patient during or after the doctor's visit. Finally, the method of Kraftson increases the amount of information the doctor must record during a visit with the patient, while the method of the application invention reduces the amount of information the doctor must record during a visit with the patient.

Additional information regarding the Kraftson reference is provided below where appropriate. A discussion of the other cited references is also provided below where appropriate.

The rejections under 35 U.S.C. § 112

Turning now to the rejections based on 35 U.S.C. § 112, second paragraph, Applicant notes that claim 4 has been amended to remove the language "and is accomplished by a member of the clinical staff," claims 5 and 14 have been amended to replace "scanner" with "scanning type machine," and claim 17 has been amended to depend from claim 2 instead of claim 8. Regarding the rejection of claim 6, claim 6 does not recite a "scanner" as asserted in the Office Action, therefore Applicant assumes this rejection was made in error.

Applicant believes that all claims presently conform to the requirements of § 112.

The rejection of claim 1 under 35 U.S.C. § 102(b)

In the Office Action, claim 1 was rejected under 35 U.S.C. § 102(b) as being anticipated by Kraftson. Applicant initially notes that claim 1 has been amended to recite "wherein the patient's electronic medical record contains patient-specific, clinical

information regarding the patient's health."

A "claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *(Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628 (Fed. Cir. 1987); MPEP § 2131). Furthermore, the "identical invention must be shown in as complete detail as is contained in the . . . claim." *(Richardson v. Suzuki Motor Co.*, 868 F.2d 1226 (Fed. Cir. 1989); MPEP § 2131).

Kraftson does not teach or suggest the step of "sending the formatted data to an assigned location for importing into the patient's patient-specific electronic medical record, wherein the patient's electronic medical record contains patient-specific, clinical information regarding the patient's health" as recited in claim 1. The invention disclosed in Kraftson does not deal with electronic medical records that contain patient-specific, clinical information regarding the patient's health because, for example, the information gathered via the survey is stored in an anonymous database and used exclusively for statistical analyses based on patient satisfaction.

Column 6, lines 10–18 of Kraftson read:

> The System further includes a Data Analysis Processor 108 for analyzing the Physician/Patient/Management information according to selected data analysis packages such as Statistical Package for the Social Sciences (SPSS) or SAS, a Report Generation Module 110 for generating formatted reports containing results determined by the Data Analysis Processor 108, and an Outcomes Measurement Module 112 for recording and tracking performance of the System.

As can be seen, this section discloses analyzing information and generating a "formatted report," but fails to even suggest importing data into the patient's electronic medical record. As explained above, a patient's electronic medical record is not a report containing results of an automated data analysis, but rather a private record containing that patient's personal, patient-specific, medical information that is viewable by a physician at the time the patient receives care from the physician.

Furthermore, Kraftson expressly teaches that the system disclosed in

Kraftson generates two kinds of reports: 1) "a periodic report which summarizes general information about a quality level of the practice," and 2) "real time reports in response to physician queries" such as where a physician needs "information comparing the historical data concerning satisfaction of patient treatment in order for the physician to determine where a recently implemented change in treatment regimen improves or decreases patient satisfaction." (Kraftson, col. 8, lines 39–63). These reports are clearly not patient-specific electronic medical records viewable at the time of care, which is further evidenced by Kraftson's disclosure that physicians must "dial up" a report generation module, and receive "periodic practice reports" or "printed reports." (*Id.*, col. 5, lines 12–16).

It would not have been obvious to one of ordinary skill in the art to modify Kraftson to send "formatted data to an assigned location for importing into the patient's patient-specific electronic medical record, wherein the patient's electronic medical record contains patient-specific, clinical information regarding the patient's health." For example, adding information to a patient's medical record must be done in a manner that conforms with the privacy requirements described above, which, prior to Applicant's invention, was done manually with software accessible only by physicians and trained medical staff. Furthermore, Kraftson expressly teaches that the information collected from patients is anonymous satisfaction information, and that automated analyses of the information are shared among physician groups. These teachings are incompatible with the use of electronic medical records containing patient-specific, clinical information regarding the patient's health, which are subject to HIPAA and other privacy laws and regulations.

Kraftson also fails to teach or suggest the step of "arranging the data stream into a defined data structure simulating the protocol structure from a party having authorization to export data to the patient's patient-specific electronic medical record" as recited in claim 1. Column 6, lines 5–10 and column 7, lines 3–10 of Kraftson are cited in the Office Action as teaching this limitation. (OA, page 7). While this element of claim 1 has been amended since the mailing of the Office Action, Applicant will address this argument in view of the amendment to expedite prosecution.

The sections of Kraftson cited in the Office Action merely disclose the general concept of converting information to "data records having a predetermined format." As explained above, converting information to a "data record" is an entirely different matter than "arranging the data stream into a defined data structure simulating the protocol structure from a party having authorization to export data to the patient's patient-specific electronic medical record," wherein the electronic medical record contains "patient-specific, clinical information regarding the patient's health." For example, Kraftson teaches that the data record format enables automated data analyses to be shared among groups of physicians (Kraftson, col. 7, lines 47–50), which is incompatible with storing the data in the patient's personal electronic medical record, which is subject to HIPAA and other privacy laws and regulations. Thus, the invention of Kraftson does not relate to patient-specific electronic medical records with clinical information regarding the patient's heath, but rather relates to creating anonymous data records relating to patient satisfaction. (*See supra*, section titled "Summary of U.S. Patent No. 6,151,581 to Kraftson").

The rejection of claim 18 under 35 U.S.C. § 103(a)

Turning now to the rejection of claim 18, Applicant initially notes that claim 18 has been amended to recite "communicating the formatted data to an electronic medical record interface and adding the information to the patient's personal medical record, *wherein the patient's personal medical record contains patient-specific, clinical information regarding the patient's health*."

In the Office Action, claim 18 was rejected as being unpatentable over Kraftson for similar reasons as claim 1. Applicant respectfully disagrees. Kraftson does not teach or suggest the limitation of "formatting the machine-processable data with the computer so that the data is in a form that may be communicated to an electronic medical record that is personal to the patient," wherein the medical record contains "patient-specific, clinical information regarding the patient's health." Applicant addressed a similar

rejection above in relation to claim 1, therefore the arguments set forth above in relation to claim 1 apply to this element of claim 18.

Kraftson further fails to teach or suggest the limitation of "communicating the formatted data to an electronic medical record interface and adding the information to the patient's personal medical record, wherein the patient's personal medical record contains patient-specific, clinical information regarding the patient's health." As explained above, the invention of Kraftson does not deal with patient-specific electronic medical records, but rather creates anonymous data records containing patient satisfaction information. Thus, not only does Kraftson not disclose communicating data to a patient-specific electronic medical record via an interface of the record, there is no need for the invention of Kraftson to perform this function because the data collected by Kraftson is not intended to be used with patient-specific electronic medical records.

Further regarding claim 18, Kraftson does not teach or suggest "presenting the information to a physician as part of the patient's personal electronic medical record." As explained above in the section titled "[t]he application invention," the method of Kraftson requires the doctor to collect information and request reports based on that information separately from the doctor's existing patient chart or file as evidenced by the fact that the doctor has to "dial up," "receive periodic practice reports," or "printed reports" to view the collected information—this is clearly not how doctors use patients' medical records.

It would not have been obvious to modify Kraftson to add patient-submitted information directly to the patient's electronic medical record because methods of modifying a patient's electronic medical record at the time the invention was made required direct access by a physician or member of the physician's staff. Furthermore, Kraftson teaches away from adding patient-submitted information to a patient's electronic medical record because the information collected from a patient, as taught by Kraftson, relates to patient satisfaction, which is not included in a patient's medical record. Furthermore, the information is stored to optimize automatic data analysis, as explained above. These teachings are incompatible with the use of electronic medical records, which contain

physician's records that are maintained in privacy.

The rejection of claim 20 under 35 U.S.C. § 103(a)

Turning now to the rejection of claim 20, Applicant initially notes that claim 20 has been amended to recite "communicating the formatted data to an electronic medical record interface engine to automatically add the information to the patient's personal electronic medical record, *wherein the patient's personal electronic medical record contains patient-specific, clinical information regarding the patient's health*."

First, Applicant submits that none of the prior art references of record teach or suggest the steps of "receiving from the patient, prior to a visit with a physician, a machine-readable printed form filled out by the patient and containing information about a health status of the patient including the patient's medical history, environment, and symptoms; electronically scanning the printed form to convert the information to machine-processable data and to communicate the data to a computer," and "formatting the machine-processable data with the computer so that the data is in the form of a Health Level Seven laboratory record, wherein the laboratory record includes the information from the printed form and information identifying an electronic medical record that is personal to the patient."

These steps involve formatting data including "the patient's medical history, environment, and symptoms" so that the data is in the form of an HL7 laboratory record. This aspect of the invention is not contemplated by the prior art. In the Office Action, the Examiner concedes that "Kraftson . . . does not expressly disclose the specific formats that are accommodated by the system" (OA, page 11), but argues that "Johnson discloses a system/method for receiving and formatting data so that the data is in the form of an HL7 laboratory record [at column 7, lines 58–67]." *Id.* Applicant respectfully disagrees.

First, it should be appreciated that the invention disclosed in Johnson involves a central medical record repository for storing medical record documents,

extracting data from the documents to identify the documents and associate stored medical records with particular patients, and enabling users to access documents associated with a patient. (*E.g.*, Johnson, abstract; col. 2, lines 13–37). Johnson does not discuss the process of creating or supplementing an electronic medical record or an HL7 record, but rather simply storing and accessing medical record documents.

The portion of Johnson cited in the Office Action (col. 7, lines 58–67) reads as follows:

> Neither the documents ingested by the data repository engine nor the data they contain need conform to predefined formats for data extraction to take place using a variety of methods. The document may contain structured data, unstructured data, or both. Structured data includes, for example, fielded data, such as database tables, and other types of formatted data files. ***Examples of medical records which include structured data are lab database tables, research database tables and other types of data files which are formatted according to predefined formats such as HL7.*** Structuring of the data enables ready identification of the fields or data elements containing data values to be extracted. Examples of unstructured data or, in other words, information which contains no data structure, includes free form text in ASCII format or word processing formats, graphs, and compound documents. Examples of documents with unstructured data include result reports status reports, and patient registration forms. The extraction rules for each type of document are stored in the knowledge base 218 and include, various methods for extracting data from unstructured or structured data sources, or both, depending on the type of document and the specific data to be extracted. The specific rules are developed from knowledge concerning the document that is provided by subscribers or that is gleaned from medical records actually submitted by medical providers.

(Emphasis added).

While Johnson makes mention of "lab database tables" that are "formatted according to predefined formats such as HL7," it is strictly in the context of storing and accessing pre-existing tables, and is completely unrelated to the creation of an HL7 laboratory record or an electronic medical record.

Furthermore, it would not have been obvious to one skilled the art to modify Kraftson or Johnson to include the step of formatting data including "the patient's medical history, environment, and symptoms" so that the data is in the form of a "Health Level

Seven laboratory record," as recited in claim 20, because the prior art teaches using HL7 laboratory records exclusively for traditional laboratory tests, such as blood tests, and does not contemplate using HL7 laboratory records to communicate information relating to the patient's "medical history, environment, and symptoms" as recited in claim 20. Furthermore, a skilled artisan will recognize that HL7 cannot be used with the system taught by Kraftson because HL7 requires the use of patient-specific identifiers, which cannot be present in the anonymous records disclosed by Kraftson.

Applicant has submitted various references that provide evidence that HL7 laboratory records have been used exclusively for traditional laboratory tests. The healthcare industry is standardizing the format in which data is communicated from laboratories to health care providers, such as hospitals and doctors' offices, and to that end has created the Logical Observation Identifier Names and Codes (LOINC) database. The LOINC database is a list of tests and matching codes used to identify each test. The following discussion shows that the laboratory tests included in the LOINC database are strictly traditional laboratory tests, such as blood tests, urine tests, and so forth, illustrating that the prior art did not contemplate—and indeed still does not contemplate—including medical history, symptom, and environment information in HL7 laboratory records.

The article entitled "LOINC, a Universal Standard for Identifying Laboratory Observations: A 5-Year Update" by McDonald et al. ("McDonald"), explains that the

> "Logical Observation Identifier Names and Codes (LOINC) database provides a universal code system for reporting laboratory and other clinical observations. Its purpose is to identify observations in electronic messages such as Health Level Seven (HL7) observation messages, so that when hospitals, health maintenance organizations, pharmaceutical manufacturers, researchers, and public health departments receive such messages from multiple sources, they can automatically file the results in the right slots of their medical records, research, and/or public health systems."

(McDonald, page 2, emphasis added).

Thus, the LOINC is a universal standard for formatting laboratory records. McDonald further explains that

> "[a]s of July 2002, the LOINC database carried records for more than 30,000

> different observations. Each record carries the formal six-part LOINC name; the LOINC code, a number with a check digit (see Table 1); the observation class (e.g., chemistry, hematology, and radiology); related names (to assist searches of the database); and other attributes."

(McDonald, page 5, emphasis added).

Therefore, the LOINC database is a standard for communicating laboratory records, such as HL7 laboratory records, to hospitals from laboratories and relates only to traditional laboratory test measurements, such as "chemistry, hematology, and radiology."

The article entitled "Logical observation identifier names and codes (LOINC) database: a public use set of codes and names for electronic reporting of clinical laboratory test results" by Forrey et al. ("Forrey"), also discusses the character and purpose of the LOINC database. Forrey explains that the LOINC database provides a universal set of test identifiers that all laboratories may use to electronically communicate test results from laboratories to the laboratories' clients via standards such as HL7. (Forrey, page 81).

Forrey explains that "each LOINC observation name identifies a distinct laboratory observation" and includes up to six parts, where the six parts are listed in table 1. (Forrey, page 83). One of the parts listed in table 1 is the "[k]ind of property measured or observed." On page 84, Forrey explains that "[a] selected list of the most common LOINC kinds of properties is shown in Table 3." Table 3 lists the following properties: substance concentration; catalytic concentration; catalytic content; mass concentration; mass content; mass concentration ratio; mass rate, for excretions; and volume rate, for clearances. These properties clearly related only to traditional laboratory tests. This is but one example.

In summary, Forrey and McDonald show that the LOINC database of laboratory test codes is limited to traditional laboratory tests, such as chemical, hematological, and radiological tests. Because the LOINC database is intended to include a comprehensive or nearly comprehensive list of tests communicated between laboratories and healthcare providers, the prior art clearly does not contemplate formatting information relating to medical history, environment, and symptoms into an HL7 laboratory record and communicating the record to an electronic medical record interface engine, as recited in

claim 20.

Furthermore, these various references relating to the LOINC database demonstrate that the prior art did not contemplate formatting data received from a patient's questionnaire so that the data is in the form of an HL7 laboratory record. Rather, the references show that only data derived in a laboratory will be so formatted.

Also regarding claim 20, Kraftson does not teach or suggest "presenting the patient's personal electronic medical record to the physician during the patient's visit with the physician, wherein the electronic medical record includes the information from the printed form." As explained previously, Kraftson expressly teaches collecting information from a patient during or after a treatment session, therefore such information could not be presented to the physician as part of the patient's electronic medical record during the visit. Furthermore, Kraftson teaches away from presenting the patient-submitted information during the visit because the information relates to the patient's satisfaction with the doctor's services, which the patient cannot assess until the visit is complete.

For at least the reasons set forth above, applicant respectfully submits that claims 1, 2, 4–6, 9–11, 13–14, and 17–21 are now in allowable condition and requests a Notice of Allowance.

In the event of further questions, the Examiner is urged to call the undersigned. Any additional fee which is due in connection with this amendment should be applied against our Deposit Account No. 19-0522.

Respectfully submitted,
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